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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,712	06/01/2001	Marina V. Backer	102131-200	4250

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EXAMINER
SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
1635	6

DATE MAILED: 04/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,712	BACKER ET AL.	
	Examiner	Art Unit	
	Richard Schnizer	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-45, drawn to a molecular delivery vehicle, classified in class 514, subclass 1.

II. Claims 46, 48, 49, 50, 52, and 53, drawn to a nucleic acid comprising segments encoding an S peptide and a human VEGF, classified in class 536, subclass 23.5.

III. Claims 47 and 51, drawn to an isolated S peptide, classified in class 530, subclass 350.

IV. Claims 47 and 55 drawn to an isolated human VEGF, classified in class 530, subclass 350.

V. Claims 47 and 55, drawn to an isolated polypeptide comprising a fusion protein comprising an S peptide and a human VEGF, classified in class 530, subclass 350.

VI. Claims 54, 56, and 57, drawn to an isolated nucleic acid comprising segments encoding S protein and a human VEGF, classified in class 536, subclass 23.5.

VII. Claim 55, drawn to an isolated S protein, classified in class 530, subclass 350.

VIII. Claim 55, drawn to an isolated polypeptide comprising a fusion protein comprising an S protein and a human VEGF, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The molecular delivery vehicle of group I is related to the nucleic acids of groups II and VI because these nucleic acids could be used to produce the targeting protein of the molecular delivery vehicle. The inventions are distinct because molecular delivery vehicle may be constructed using other targeting proteins such as antibodies. Further, the nucleic acids of groups II and IV could be used for other purposes, such as the generation of hybridization probes.

The molecular delivery vehicle of group I is related to the peptides and polypeptides of groups III-V, VII, and VIII because these peptides and polypeptides could be used as targeting proteins in the process of making the molecular delivery vehicle. The inventions are distinct because molecular delivery vehicle may be constructed using other targeting proteins such as antibodies. Further, the peptides and polypeptides of groups III-V, VII, and VIII could be used for other purposes, such as the generation of antibodies.

The nucleic acids of group II are related to the peptides and polypeptides of groups III-V because the nucleic acids may encode these peptides and polypeptides, and may be used in the production of these peptides and polypeptides. The inventions are distinct because the polypeptide products can be made by other and materially distinct processes, such as purification from natural sources or organic synthesis. Further, polynucleotides can be used for processes other than the production of proteins, such as nucleic acid hybridization assays.

The nucleic acids of group II are related to the nucleic acids of group VI in that they may both encode a human VEGF. The inventions are distinct because they must encode S peptide,

and S protein, respectively. These are structurally and functionally distinct molecules, and the resulting nucleic acids must be structurally and functionally distinct as well.

The nucleic acids of group II are unrelated to the isolated proteins of groups VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case nucleic acids of group II cannot be used to produce the polypeptides of groups VII and VIII, and the nucleic acids have different functions, modes of operation and effects. Further the specification does not disclose the combined use of these inventions together for any purpose.

The isolated S-peptide of group III is related to the S peptide-VEGF fusion protein of group V in that both of these molecules can bind to S protein. The inventions are distinct because the S peptide cannot perform the receptor-binding function of VEGF.

The isolated S peptide of group III is distinct from the VEGF of group IV because it has a different structure and a different function. The S peptide functions to bind to S protein, whereas VEGF cannot perform this function.

The isolated S peptide of group III is unrelated to the nucleic acid of group VI. The S peptide is not encoded by the nucleic acid, and is not disclosed as being capable of use with the nucleic acid.

The isolated peptide of group III is related to the S protein and S protein fusion protein of groups VII and VIII in that it may be used to bind to these proteins. The inventions are distinct because the isolated S peptide may be used for different purposes such as the production of anti-S peptide antibodies.

The isolated VEGF of Group IV is related to the fusion proteins of groups V and VIII because its structure is present in these fusion proteins. The inventions are distinct because VEGF likes the binding characteristics of the fusion proteins, i.e., it cannot bind to either S peptide or S protein, and therefore cannot be used for the same purpose as these fusion proteins.

The isolated VEGF of group IV is related to the nucleic acid of group VI because the nucleic acid may encode VEGF. The inventions are distinct because the they are distinct inventions because VEGF can be made by other and materially distinct processes, such as purification from natural sources. Further, the nucleic acid can be used for processes other than the production of VEGF, such as nucleic acid hybridization assays.

The isolated VEGF of group IV is distinct from the S protein of group VII because it has a different structure and a different function. The S protein functions to bind to S peptide, whereas VEGF cannot perform this function.

The S peptide-VEGF fusion protein of group V is distinct from the nucleic acid of group VI and the polypeptides of groups VII and VIII because it has a distinct structure and function which is lacking from each of these molecules. As such it is useful for distinct purposes. For

example, none of the molecules of groups VII and VIII can be used to bind to the S protein, which is the function of the S peptide.

The nucleic acid of group VI is related to the polypeptides of groups VII and VIII because it may encode the polypeptides. The inventions are distinct because the nucleic acid can be used for processes other than the production of VEGF, such as nucleic acid hybridization assays.

The isolated S protein of group VII is related to the S protein-VEGF fusion protein of group VIII in that both of these molecules can bind to S peptide. The inventions are distinct because the S protein cannot perform the receptor-binding function of VEGF.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Claims 1-45 are generic to a plurality of disclosed patentably distinct species comprising carrier molecules including polysaccharides, polylysine, polyethyleneimine, poly(vinyl alcohol), poly(divinyl) ether-co-maleic anhydride, polyethylene glycol, polymethyl methacrylates, polyanhydrides, polyesters, polyacrylic acids, polyurethanses, N-(2-hydroxypropyl) methacrylamide), derivatized polyethyleneglycols, co-polymers, derivatized copolymers, liposomes, derivatized liposomes, dendrimers, derivatized dendrimers, viral particles, bacteriophage particles, bids, and nanoparticles. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-45 are generic to a plurality of disclosed patentably distinct species of compounds including nucleic acids, peptides, proteins, viruses, viral particles, chemotherapeutic agents, paramagnetic agents, radioactive agents, and fluorogenic agents. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-45 are generic to a plurality of disclosed patentably distinct species of targeting portions comprising wild type S proteins, mutant S proteins, ribonuclease A, cellulose, calmodulin, and streptavidin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 31-45 are generic to a plurality of disclosed patentably distinct species comprising pharmaceutically acceptable carriers including water, gelatin, lactose, starch, magnesium stearate, talc, plant oils, gums, alcohol, petroleum jelly, and buffered saline. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.